

REMARKS

In response to the Office Action dated June 27, 2008, Applicants respectfully request reconsideration.

Allowable Subject Matter

Applicants thank the Examiner for indicating that claims 13-15 and 24-26 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 1 has been amended to include all of the limitations recited in claim 13, and claims 14-15 have been amended to depend from the amended claim 1. Applicants respectfully assert that amended claims 1, 14, and 15 are patentable, and a notice to that effect is respectfully requested.

Regarding claim 16, from which claims 24-26 depend, as will be discussed in more detail below, Applicants respectfully assert that claim 16 is patentable over the cited references.

Claim rejections

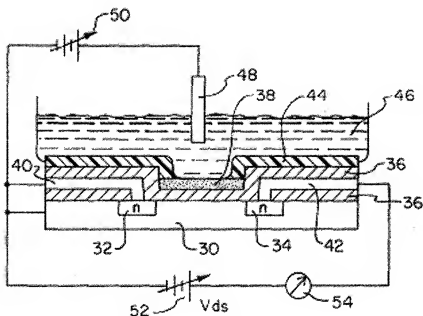
Claims 1-4, 7, 8, 9, 11, 16, and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,020,830 (Johnson).

Claims 1, 2, 4, 5, 7-9, 10, 16, 19, 21, 23, and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,822,566 (Newman).

Claims 6, 12, 17, 18, 20, 22, and 28-32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Newman.

Applicants respectfully assert that claim 1 is patentable over Johnson and Newman. Notwithstanding this, Applicants have amended claim 1 to include all of the limitations recited in claim 13, which the Examiner indicated would be allowable. Claims 2-9, 11-12, 14-15, and 32, which depend from independent claim 1, are thus patentable. Claims 10 and 13 have been canceled, therefore, any rejection of these claims is moot.

Johnson, either alone or in view of Newman, does not teach, suggest, disclose, or make obvious the claimed subject matter of any of the present claims. Figure 2 of Johnson discusses a selective chemical sensitive field-effect transistor:



The chemical sensitive FET includes insulator material 36, chemical-sensitive membrane 38, and a conductive layer 40. Johnson, col. 4, l. 57 – col. 5, l. 67. Assuming, *arguendo*, that the insulator material 36 is a substrate, and that membrane 38 and the conductive layer 40 are electrodes, Figure 2 of Johnson still does not show that the either one of the membrane 38 or the conductive layer 40 is on both sides of a single piece of the insulator material 36. In contrast to Figure 2 of Johnson, claim 16 recites a second electrode, wherein the second electrode comprises a top electrode layer arranged on the first side of a substrate, said top electrode layer being arranged, at least in part, around the first electrode, and a bottom electrode layer arranged on a second side of the substrate, said bottom electrode layer having a larger extension than said top electrode layer.

Regarding claim 28 and the Examiner's suggestion that it is well known to use a strap or other attachment to hold an in vivo (sic) device in place on the body, the FET discussed in Figure 2 of Johnson cannot be attached in vitro to an arm or a leg because it would not work (e.g., because the FET shown in figure 2 is immersed into the solution 46 (see col. 5, l. 65 – col. 6, l. 12)). Thus, even if the FET shown in figure 2 of Johnson disclosed the electrode recited in claim 28, a person of ordinary skill in the art still would

not have added a band to the FET for in vitro use on an arm or a leg, as recited in claim 28.

Newman, either alone, or in view of Johnson, does not teach, suggest, disclose, or make obvious the claimed subject matter of any of the present claims. Figure 1a of Newman discusses a sensor:

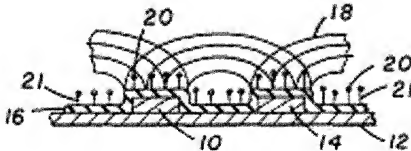


FIG. 1a

The sensor includes a first conductor 10, a substrate 12, a second conductor 14, and an insulating passivation layer 16. Col. 4, ll. 40-65. Newman does not show that either one of the conductors 10 or 14 is on both sides of either the substrate 12 or the insulating passivation layer 16. In contrast to Newman, claim 16 recites a second electrode comprising a top electrode layer arranged on the first side of the substrate, and bottom electrode layer arranged on a second side of the substrate.

Regarding claim 28 and the Examiner's suggestion that it is well known to use a strap or other attachment to hold an in vivo (sic) device in place on the body, the sensor discussed Newman (similar to the FET of Johnson) cannot be attached in vitro to an arm or a leg because it would not work (e.g., Newman's sensor is either immersed into the fluid being tested, or the fluid medium is poured onto the sensor (see col. 4, l. 66 – col. 5, l. 3)). Thus, even if the sensor shown in figure 1a of Newman disclosed the electrode recited in claim 28, a person of ordinary skill in the art still would not have added a band to the sensor for in vitro use on an arm or a leg, as recited in claim 28.

Furthermore, regarding the obviousness rejections made by the Examiner, Applicants respectfully assert that the Examiner has not established at *prima facie* case of obviousness under 35 U.S.C. § 103. The U.S. Code and the M.P.E.P. require that

Examiners provide an explanation to support an obviousness rejection under 35 U.S.C. § 103 such that the applicant can be given fair opportunity to reply. *See* 35 U.S.C. § 132; M.P.E.P. §§ 706.02(j), 2141. Because the cited references do not suggest the claimed subject matter themselves, the Examiner must present a convincing line of reasoning as to why a person of ordinary skill in the art would have found the claimed invention obvious in light of the teachings of the references. *See* M.P.E.P. § 706.02(j). Applicants respectfully assert that the Examiner's reliance on "official notice" and the synonymous conclusion that certain aspects of the claims "are a mere matter of design choice" do not satisfy the "convincing line of reasoning" standard.

The use of official notice by an Examiner in a final rejection should be rare. *See* M.P.E.P. § 2144.03(A). An Examiner is not permitted to simply reach conclusions based on his own understanding, experience, or his assessment of what would be basic knowledge or common sense. *Id.* To the extent that an Examiner does use official notice without providing explicit documentary evidence, the Examiner must only do so where the facts are so well known that they are capable of instant and unquestionable demonstration as being well known. *Id.* Thus, Applicants should be presented with the explicit basis on which the Examiner justifies his use of official notice such that Applicants may adequately traverse the rejection. *Id.*, at (B).

In light of the foregoing, applicants respectfully assert that the Examiner's numerous statements of official notice, and "mere design choices" are insufficient. Specifically, however, Applicants will address the Examiner's statement that "it is well known to use a strap or other attachments means to hold an in vivo (sic) device in place on the body" and that it is a "mere matter of design choice" to provide one electrode on each side of the substrate or both on the same side.

Regarding the Examiner's statement about the use of a strap, Applicants respectfully point out that claim 28 recites a wristband for fixing the first electrode to at least one of an arm and a leg of a body with a longitudinal axis of the first electrode being substantially parallel to the at least one arm and leg. Applicants respectfully assert that to state that it is common to use a strap, while omitting the specific manner in which the strap is used, ignores the claimed subject matter as a whole. *See* M.P.E.P. § 2141.02 ("In determining the differences between the prior art and the claims, the question under

35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.” (emphasis in original)). Thus, while it may be common knowledge to use a strap to hold a device in place on a body, it is not capable of “instant and unquestionable demonstration” to use a strap to fix an electrode to an arm or leg with a longitudinal axis of the electrode being substantially parallel to the arm and leg. Furthermore, in any event, as discussed above, the devices discussed in Johnson and Newman will not function if attached in vitro to an arm or leg because both devices require contact with the substance being tested.

Regarding the Examiner’s statement that the placement of the top and bottom electrode layers would have been a “mere matter of design choice,” Applicants respectfully assert that the Examiner is i) overlooking the differences between the claimed subject matter and the cited references, and ii) the challenges overcome by the Applicants. Without a doubt, Applicants made the “choice” to include a second electrode arranged on a first and second side of a substrate. However, all claimed subject matter is the result of a “choice” made by an inventor. Thus, the question when determining obviousness is not whether a choice was made, but rather whether an “obvious choice” made. Applicants respectfully assert that the Examiner has not articulated why Applicants’ purported “mere matter of design choice” would have been an obvious one to a person of ordinary skill in the art, as required under an obviousness analysis. *See e.g.* M.P.E.P. § 2141. Indeed, Applicants assert that the configuration recited in claim 16 was not the result of an impulse or whim, but rather that the configuration recited in claim 16 was claimed in order to obtain certain benefits such as the reduction of false signals.

Thus, for at least all the reasons discussed herein, independent claim 16 is patentable over Johnson and Newman because it recites at least a device for determining a concentration of glucose in at least one of an in-vitro and in-vivo specimen containing body liquid, the device including, *inter alia*, a second electrode arranged on the substrate, wherein the second electrode comprises a top electrode layer arranged on the first side of the substrate, said top electrode layer being arranged, at least in part, around the first electrode, and wherein the second electrode further comprises a bottom electrode layer arranged on a second side of the substrate, said bottom electrode layer having a larger extension than said top electrode layer.

Claims 17, and 22-27, which depend from independent claim 16, are patentable for at least the reasons discussed above with respect to independent claim 16.

Furthermore, for at least all the reasons discussed herein, independent claim 28 is patentable over Johnson and Newman because it recites at least a device for determining a concentration of a substance in body liquid of a human body including, *inter alia*, an elongate first electrode having a width substantially smaller than a length, and a wristband for fixing the first electrode to at least one of an arm and a leg of a body with a longitudinal axis of the first electrode being substantially parallel to the at least one arm and leg.


Claims 18, and 29-31, which depend from independent claim 28, are patentable for at least the reasons discussed above with respect to independent claim 28.

Conclusion

Based on the foregoing, this application is believed to be in allowable condition, and a notice to that effect is respectfully requested. If a telephone conversation with Applicant's representative would help expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at (617) 542-6000.

The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account 50-0311, Reference No. 24334-001. The Director is further authorized to charge any required fee(s) under 37 C.F.R. §§ 1.19, 1.20, and 1.21 to the abovementioned Deposit Account.

Respectfully submitted,


A. Jason Mirabito, Reg. No. 28,161
Kyle Turley, Reg. No. 57,197
Attorneys for Applicants
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY AND POPEO, PC
One Financial Center
Boston, MA 02111
Tel.: (617) 542-6000
Fax: (617) 542-2241
Customer No. 30623

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